

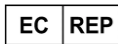


SSL-4700 HEADLIGHT SYSTEM

Operation Manual



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1. SYMBOLOGY


Symbol	Description	Symbol	Description
 or  YYYY-MM-DD	Manufacture Manufacture w/Date of Manufacture NOTE: Date may also be placed on right side of factory symbol.		Date of Manufacture (YYYY-MM-DD)
	“Authorized Representative”, European Community		“Authorized Representative”, Switzerland
	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner		European CE Mark
	Instructions for Use		Medical Device
	Supplied Non-Sterile		Unique Device Identifier
	Note		Caution: Hot Surface
	Caution		Caution: High Voltage
	Warning		Keep Dry
	Do Not Use if Damaged		Special Electrical / Electronic Disposal required.
	Storage / Shipping Temperature		Storage / Shipping Humidity
	Barometric Pressure		Product Safety Tested CSA Canada, US
	Alternating Current		Equipotentiality
	Type BF		Protective Earth (Ground)
	Power “ON” Symbol		Power “OFF” Symbol
	Indicates suitability for direct current only.		Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.

2. INTRODUCTION

Congratulations on the purchase of your new LED Headlight 4700 system.


The LED Headlight 4700 is a battery powered portable headlight with an adjustable spot and uses encrypted battery technology that requires the use of approved batteries obtained from the manufacturer or authorized distributors.

Additionally, a low battery alarm is included in this system and will beep when power is low. Decreasing the output may extend battery life and therefore the amount of warning time before powering down. This alarm is a convenience, and the user should plan for backup lighting for any application using this system; see General Warnings.

	<p>No special intervention is necessary in the event of device failure. As such, this device has no essential performance, as defined by IEC 60601-1.</p> <p>Should this device fail to operate, a suitable backup should be available for any procedure where it may be used.</p>
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3. INTENDED USE

The LED 4700 Headlight system is designed to deliver illumination from a high intensity LED for surgical site illumination.

	<p>The LED 4700 Headlight system is intended to be used in a controlled surgical setting environment by qualified medical personnel.</p> <p>The LED 4700 Headlight system is provided in a non-sterile state and is not intended to be sterilized. Refer to Cleaning Instructions provided in this manual.</p>
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4. CONTRAINDICATIONS

This device is not intended to be used for monitoring, diagnostic, or other life support functions. It is not intended to compensate for injury, handicap, replacement or modification of anatomy, or control of conception.

	WARNING	This device should <i>NEVER</i> be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.
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5. PATIENT TARGET GROUP and INTENDED USER


This device is not intended for a particular target group or groups, as the device is intended to be used in a surgical setting for illumination of a surgical site under the supervision and direction of a physician only.

6. ADVERSE EVENTS / SERIOUS INCIDENT – MEDICAL DEVICE REPORTING

Per the FDA, an Adverse Event or Serious Incident is defined as:

Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- Failure
- Malfunction
- Improper or inadequate design,
- Manufacture
- Labeling, or
- User error

	In the event of an Adverse Event or Serious Incident, the end-user should contact their distributor immediately.
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7. CLINICAL BENEFIT - DEFINITIONS

Regulation (EU) 2017/745

Article 2(53) MDR defines clinical benefit as the positive impact of a device on the health of an individual, expressed in the terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

US FDA

Clinical benefit is a favorable effect on a meaningful aspect of how a patient feels (e.g., symptom relief), functions (e.g., improved mobility) or survives as a result of treatment. • Clinical benefit may be measured as an improvement or delay in the progression of a disease or condition (as manifested by how a patient feels/functions).



The manufacture of this device makes no claims as to any Clinical Benefit to be gained by the use of this product.

8. ADVERSE EFFECTS

The manufacturer is not aware of any Adverse Effects experienced from the use of this device when properly utilized per the devices intended use. Refer to Section 6 of this documents for additional details.

9. PRIOR to USE

It is recommended that the end-user perform a functional check of the light source to ensure proper operation prior to use in a surgical procedure.

10. STORAGE CONDITIONS

- Temperature Range: -4 to 140°F (-20 to 60°C)
- Humidity Range: 30 to 95% RH non-condensing
- Barometric Pressure: 700 to 1060 hPa

11. FUNCTION of DESIGN

The LED 4700 Headlight System is a battery-operated device producing high intensity light in the visible spectrum range.

The system includes the following components:


- Headband with LED Light Module
- Battery Holster with Belt Clip
- 2 Batteries
- Battery Charger
- Replacement Headband Pads
- Joystick(s) for LED Module Adjustment




Refer to Section 15 for Assembly and Section 16 for Function Check of the LED 4700 Headlight.

12. WARNINGS / CAUTIONS

Use of this equipment may present hazards to the user and/or patient. Before operating this device, please read this operating manual thoroughly and follow all warnings, cautions, and instructions for use.

	WARNINGS	WARNING symbol indicates conditions that may cause risk to the safety of the patient or user. Failure to adhere to the follow warnings may result in injury to the patient or end user.
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- Before each procedure, carefully check the 4700 system for damage. ***DO NOT*** use if damaged.
- The 4700 produces highly concentrated light. Avoid shining light beam into the eyes of patient or surgical staff.
- Before each procedure, carefully check the battery state of charge to assure optimal duration for this procedure. The user is responsible for determining if an interruption of light output will create an unacceptable risk. Having a backup battery or backup 4700 system is advised in the event of such an occurrence.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- ***DO NOT*** modify the equipment without authorization from the manufacturer.
- The 4700 system is provided non-sterile and is not intended to be sterilized.
- This device meets CISPR 11 Class A limits and is suitable for use in hospital and industrial environments. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Performance of this device may be affected in proximity of another device and/or equipment capable of producing high levels of RF emissions. The device should be used no closer than 12 inches (30 cm) to any part of RF equipment including cables. In the event performance of this device is affected due to high levels of RF emissions, relocation of the suspected device and/or equipment producing high levels of RF emissions, or the headlight system may reduce or eliminate the problem.

	CAUTIONS	Indicates risks of improper use and/or damage to the equipment. Failure to adhere to the following cautions may result in loss of function or product damage.
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- LED high intensity headlights will produce some heat in addition to light. The high output of these headlights may cause some components to become warm to the touch. This is normal operation.
- The headlight should only be used with approved batteries supplied by the manufacturer. To order additional batteries, please call customer service 1-877-677-2832.
- **All service and repair must be performed by the manufacturer or qualified service technicians.**

	Any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.
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13. WARRANTY



Upon receipt of the product, the device should be carefully inspected for visible damage. If any defect is discovered, notification must be given immediately to the distributor.

LED Module, Headband, Battery Charger and Battery Holster

- The LED 4700 Headlight System LED Module, Headband, Battery Charger and Battery Holster come with a 3-year warranty for all workmanship and defects of material.
- Should your product prove to have such defects within the 3-year period, Sunoptic Surgical will repair or replace the product at its sole discretion without charge.
- Should the LED 4700 Headlight System require servicing during the warranty period, please contact your distributor for the appropriate Return Authorization documentation.

Battery

- The Battery comes with a 1-year warranty for all workmanship and defects of material.
- Should your product prove to have such defects within the specified warranty period, Sunoptic Surgical will repair or replace the product without charge at its sole discretion.



Warranties do not cover equipment or components that have been subjected to misuse.

15. ASSEMBLY



Ensure that the LED Module protective lens cap is removed prior to assembly.

- Insert a fully charged encrypted battery into the Battery Holster and ensure it is fully seated down on the connector at the bottom of the battery cavity.
- Should a non-encrypted battery be installed, two beeps will be heard upon insertion indicating that an incorrect battery is being used and the unit will not power up. Insert an encrypted battery and the unit will power up.
- To attach the power cable from the LED Module to the Battery Holster, insert the push-pull quick connector of the LED Module into the receptacle on the lead from the Battery Holster until it clicks in place as shown below in Figure 1.
- The connectors interlock to reduce the possibility of an undesirable disconnect thus causing the LED Module to extinguish during use.



Rotate the connectors to find the keyway and then press together.



Figure 1

- To remove the LED Module from the Battery Holster, press the small, raised button on the quick disconnect device located between the LED Module and the Battery Holster and pull straight out without twisting. See Figure 2 below.



Figure 2

16. ADJUSTING the HEADBAND and FUNCTIONAL CHECK



Inspect the wiring harness cable located on the headband to ensure that there is adequate slack in the cable. Refer to illustrated Figure 3 below for the two (2) recommended “Wire Harness Slack” locations.

- Place the headband on your head.
- You can make size adjustments by turning the knob on the rear of the headband until it feels comfortable. For more comfort you can adjust the cross band.



- Ensure a fully charged battery is installed into the Holster**
- Ensure the “ON/OFF” switch located on the Holster is in the “OFF” position prior to performing the next step.**

- Connect the LED Module wire harness connector, located on the headband, to the Holster wire harness connector. Once connected, the 4700 LED Headlight is ready for use.



The system comes with gown clips to relieve the weight of the cable from the headband. One gown clip is attached below the shoulder.




Figure 3

- The ON/OFF switch, located on the Holster, also serves as the LED light intensity control.
- Turn the LED Module “ON” and rotate the switch knob clockwise or counterclockwise to produce the desired light output.
- The LED Module also has an iris to allow the adjustment of the light beam spot diameter. Rotate the fluted iris adjustment ring on the headlight clockwise or counterclockwise for the appropriate spot diameter.
- The battery Holster is designed to be worn on a belt. Located on the rear side of the Holster is a metal belt clip that slips over and secures to a belt.



Once the battery is depleted into the last shown “block” on the power gauge, the unit will beep once to indicate low battery levels. The unit will beep twice to indicate further reductions in power before shut-down.

	CAUTION	<ol style="list-style-type: none"> 1. To avoid over-discharging of the battery pack, place the battery pack in the supplied charger once the holster beep notifying a LOW BATTERY condition exists. 2. DO NOT store batteries with low charge for extended periods of time, and DO NOT leave low charged batteries in the holster
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17. MAINTENANCE and CLEANING

Storing the headlight system in a safe place will prolong the life of the unit. The following guidelines will help in sustaining the headlight system useful life:


Storage

- Keep the optical faces of the LED Headlight lens from touching hard surfaces, which may cause scratches on the surface. Scratches on the surface will diminish the light output. Using the lens cap during transport will help protect the lens.

Cleaning


	CAUTION	<ol style="list-style-type: none"> 1. Do not use strongly caustic or acidic cleansers such as “Clorox” hypochlorite bleach, ammonia, muriatic acid, or similar products. Do not use acetone, methyl ethyl ketone or halogenated / chlorinated hydrocarbon solvents or cleansers containing any of these restricted compounds. 2. DO NOT AUTOCLAVE !
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- The headlight module and headband can be wiped down with commercially available cleansers commonly used for disinfection of electronic equipment in hospitals such as ethyl or isopropyl alcohols, disinfecting sprays containing quaternary ammonium compounds, or hydrogen peroxide. The lens should be cleaned only with lens tissue, available in any camera store; follow the directions on the package.
- The Neoprene wraps can be removed from the headband by undoing the clasps. They can then be cleaned by either hand washing in warm soapy water or machine washed.
- Apply cleaning agents by light spray or dampened towels. Do not pour liquids onto the device. Do not allow liquids to enter the device seams or ventilation openings.

	CAUTION	<i>Follow all applicable bloodborne pathogen procedures as required by OSHA and/or your hospital, when cleaning and disinfecting the product.</i>
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18. SMART BATTERY

The 2054 series smart li-ion battery pack is supplied with the LED 4700 Headlight System.

	For additional information pertaining to the Battery, contact your distributor.
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	WARNINGS	<p>WARNING symbol indicates conditions that may cause risk to the safety of the patient or user.</p> <p>Failure to adhere to the following warnings may result in injury to the patient or end use</p>
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- Upon initial receipt and before each use, inspect each battery for damage and charge status. Do not attempt to charge a damaged battery.
- Charge batteries completely prior to use if needed.
- Do not expose the battery to heat, fire, mechanical shock, or store in direct sunlight.
- Do not open or dismantle the battery.
- Do not use this equipment in the presence of a mixture containing flammable anesthetic and/or air or oxygen or nitrous oxide.
- Do not sterilize, immerse, or expose the battery to water, solvents, lubricants, or other chemicals to clean the charger unless otherwise directed. Do not allow water to collect in the battery contacts. Keep clean and dry.
- Do not short-circuit, crush, or shred the battery.
- Do not store the batteries in a location in which the battery may be subject to short circuit conditions from metal objects.

- In the event of a battery leakage, do not allow the liquid to come in contact with skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Do not use any charger other than a smart battery charger supplied by the manufacturer.
- Ensure correct battery orientation is followed before placing it into a device.
- Do not attempt to force a battery into a device.
- When possible, remove the battery from equipment when not in use.
- Do not over-discharge the battery. Ensure that a battery is promptly charged in an appropriate charger if the battery pack has less than 10% charge.
- Do not store batteries for more than one month in a discharged state.
- Do not store batteries for more than one year without recharging.

Battery Operation

- The 2054 series battery is equipped with a charge fuel gauge that displays the relative charge state of the battery.
NOTE: On some batteries, the “Charge Fuel Gauge” may be located on the top of the battery.
- To activate the fuel gauge, press the small circular button next to the gauge. Each LED on the fuel gauge represents 25% of the fully charged capacity. Below is the fuel gauge legend and a pictorial view of battery:
 - All four LEDs illuminated – Capacity = 76 – 100%
 - Three LEDs illuminated – Capacity = 51 – 75%
 - Two LEDs illuminated – Capacity = 26 – 50%
 - One LED illuminated – Capacity = 10 – 25%
 - One blinking LED – Capacity < 10%



Charging the Battery


- The 2054 series battery should only be charged with the supplied Smart Charger supplied with the LED 4700 Headlight System. To charge, orient the battery to line up the charger and battery contacts, and place the battery into the charger slot. Do not force the battery into the slot.

Cleaning

- Remove the battery from the host device. Clean the exterior of the battery with a cloth that has been dampened (not dripping) using a hospital disinfectant. Follow applicable hospital protocols during cleaning and dry immediately.


19. SMART CHARGER and CALIBRATOR

The Smart Charger is intended to charge 2054 series smart li-ion battery packs supplied with the LED 4700 Headlight System.


	CAUTIONS	Indicates risks of improper use and/or damage to the equipment. Failure to adhere to the following cautions may result in loss of function or product damage.
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- Upon initial receipt and before each use, inspect each battery and charger for damage. Do not attempt to charge a damaged battery. Do not attempt to operate the charger if the cord and/or plug appear to be damaged, such as cuts, bent pins or contacts, and/or cracks.


- Do not expose the charger to heat, fire, or mechanical shock. Place the charger in a cool spot, away from any heat sources.
- Do not use this equipment in the presence of a mixture containing flammable anesthetic and/or air or oxygen or nitrous oxide.
- Do not sterilize, immerse, or expose the charger, or power supply to water, solvents, lubricants, or other chemicals to clean the charger unless otherwise directed. Do not allow water to collect in the bays or on top of the charger. Do not allow water to enter the power connection on the back of the charger. Keep clean and dry.
- Do not short-circuit, crush, open, shred, incinerate, or dismantle the charger or the power supply brick.
- Do not modify or change the power cord. The power cord should be plugged into a hospital grade outlet.
- Do not bend the power cord forcibly or place a heavy object on it. This will damage the cord and may cause fire or electrical shock.
- Use only the charger and charger accessories as intended. Do not modify the device.
- Do not operate the charger at a different voltage than what is listed on the unit and in this Instructions for Use.
- Unplug the power supply from the wall socket during extended periods on non-use. Disconnect the power plug by pulling from the plug housing and not the cord.
- If the charger or the battery generates excessive heat, becomes discolored, emits an odor, or leaks disconnect the power cord from the wall socket immediately.
- Do not locate the Battery Charger in the vicinity of a patient. In accordance with EN60601-1-1, the horizontal distance must be at least 1.5 meters.

	<p>CAUTION</p>	<p>To avoid over-discharging of the battery pack, place the battery pack in the supplied charger once the holster begins to notify of low charge. DO NOT store batteries with low charge for extended periods of time, and DO NOT leave low charged batteries in the holster</p>
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- Do not insert a fully charged battery into the charger repeatedly. Due to the high initial charge, the battery could be overcharged which could lead to damage to the battery and to the battery charger.


	<p>This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. If this device is causing interference with other electrical equipment, relocate the charger further away from the other equipment.</p>
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20. BATTERY CHARGER OPERATION, CLEANING INSTRUCTIONS, TROUBLESHOOTING

	<p>For additional information pertaining to the Battery Charger, contact your distributor.</p>
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Operation

- Place the charger on a stable surface. Plug the output connector of the external AC/DC power supply into the DC input located on the rear of the charging station. Then plug the external AC/DC power supply into an AC outlet.
 If desired, route the AC/DC cable under the cable retention clip located on the rear of the charger, and press down on the clip until it clicks. To release the cable retention clip, slide the clip laterally until it clears the hook.
- The charge process will start after inserting a battery pack into the slot. The charge indication will be displayed. Refer to Table 1.

	<ol style="list-style-type: none"> 1. The unit will become warm during normal operation. This does not indicate a malfunction. 2. Prevent metallic objects from coming into contact with the metal parts of the DC plug of the power supply. If this happens, a short may occur and the unit may be damaged. 3. Ensure the battery has proper orientation before insertion. Do not attempt to force a battery into the slot as this may damage the contacts.
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LED Indicator	Charging Condition
One Time Red/Orange/Green	Self-test: Charger is ready for use
Red/Green Blinking	The battery was not recognized as a Smart Battery. Either a conventional battery is inserted or an extremely discharged Smart Battery. If it is a Smart Battery, it will be reactivated within 15 minutes and recharged. If this is not the case, the LED will light red – see below.
Orange blinking	The battery is currently being calibrated
Orange light	The inserted battery is the correct type and is currently being charged.
Green light	The battery is charged and ready for use
Red blinking	The battery is too hot or too cold to be charged without damage. If the battery is too cold, it will be charged as soon as it has warmed up sufficiently. If the battery is too hot, it should be removed to cool down.
Red light	Either: <ol style="list-style-type: none"> 1. The battery is badly damaged and must be replaced 2. It is a conventional battery which cannot be recharged

Table 1 - LED Indicator Legend

	CAUTION	<p>If a RED LED is lit on a bay, the battery of the corresponding bay should be removed from the charger and its contacts checked. Install the battery pack again. If the RED LED illuminates again, remove the battery pack from the charger, tag battery as defective and quarantine.</p>
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Cleaning Instructions

- Disconnect the Charger from the power source.
- Clean the exterior of the charger with a cloth that has been dampened (not dripping) using a hospital disinfectant. Follow applicable hospital protocols during cleaning and dry immediately.

Battery Charger Troubleshooting

SYMPTOM	POSSIBLE CAUSES/SOLUTIONS
Battery not charging	<ul style="list-style-type: none"> • Ensure charger power cord is plugged in to the AC power outlet. • Ensure DC connector is plugged into the back of the charger • Ensure battery is properly seated in the charger bay. • If repeated attempts to charge the battery have failed, the battery may be faulty. Replace the battery. • The charger may have a faulty power cord and/or power brick. Replace the power cord and/or power brick.
Charger LED indicator not working	<ul style="list-style-type: none"> • Ensure charger power cord is plugged in to the AC power outlet. • Ensure battery is properly seated in the charger bay. • The charger may have a faulty power cord and/or power brick. Replace the power cord and/or power brick.

21. END OF PRODUCT LIFE



In accordance with the European Waste from Electrical and Electronic Equipment (WEEE) directive, we encourage our customers to recycle this product and/or components whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

In the US a list of recyclers in your area can be found at: <http://www.eiae.org/>.